4-30-91

## IRB BRANCH REVIEW - TSS

Record Number(s)

D160130

IN 3/27/91 OUT 4/30/91

EFFICACY

FILE OR REG. NO. 64439-R

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 12/4/90

DATE OF SUBMISSION 11/21/90

DATE SUBMISSION ACCEPTED 3/27/91

TYPE PRODUCTS(S): I, D, H, F, N, R, S

DATA ACCESSION NO(S). none

PRODUCT MGR. NO. 16

PRODUCT NAME(S) MOLE MED MOLE REPELLANT(sic) AND LAWN PROTECTANT

COMPANY NAME Dinah Pickett

SUBMISSION PURPOSE registration

CHEMICAL & FORMULATION 66% Oil of Ricinus and [redacted] liquid mixture

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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Efficacy Review: MOLE MED MOLE REPELLANT AND LAWN PROTECTION, 64439-R
Dinah Pickett
Aurora, IN 47001

200.0 INTRODUCTION

INERT INGREDIENT INFORMATION IS NOT INCLUDED

200.1 Uses

A 66% Oil of Ricinus and [redacted] liquid mixture proposed for registration as a "REPELLANT" to be used "to rid your yard of moles."

200.2 Background Information

See efficacy review of 6/19/90 on a prior submission, dated 5/8/90, which was not considered by RSB to be a registration application, despite its containing labeling, a Confidential Statement of Formula (CSF), and a pesticide registration application form (EPA Form 8570-1). No materials from the earlier submission appeared in the product jacket until 4/29/90 when I inserted a copy of my review of 6/19/90. The remaining materials from that submission probably are filed under correspondence number 16-817. These materials should be placed at the back of the jacket for 64439-R.

Subsequent to the initial submission, the applicant has retained the Covington, KY, law firm of Cobb & Oldfield to assist in the process of applying for pesticide registration.

An attempt of 11/21/90 to file a registration application failed the data submission screen. On 2/25/91, EPA wrote to Dinah Pickett indicating further data and formatting requirements. The material routed for my review consists of three efficacy reports.

201.0 DATA SUMMARY

The efficacy reports consist of one-page forms filled out partially by typing and partially in ink. These forms all are signed by Eldon Pickett, the originator of the submission of 5/8/90 and apparently the husband of Dinah Pickett.

The reports provide information regarding three alleged applications of the product. These applications are said to have been made on 1/21/90, 3/19/90, and 5/4/90. (This product may have been marketed prior to the 5/8/90 submission which, in turn, may have been precipitated by intervention by a State regulatory agency in Indiana.) The reports' completion dates are 11/21/90, 10/15/90, and 11/15/90. These dates are some 6-10 months after the dates given for initial treatments. The dates are typed in.



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The report of 11/21/90 states that two applications were made to a 4,500-square-foot mixed-grasses area. According to the report, evidence of "mole activity was present" four days after treatment, and after three days of rain. After a second treatment on 2/1/90, mole activity was said to be absent for the next four months. The two treatments (or maybe each treatment) required a 32-ounce bottle of MOLE MED.

The report of 10/15/90 describes treatment of a 2400-square-foot lawn. Moles were said to have abandoned treated areas within a day of treatment, as determined by the leveling of runs and mounds and by the absence of mole activity for four weeks. Two weeks later, evidence of moles "reappeared." The area was treated again, and new runs did not appear "for the balance of 1990 season." One 8-ounce bottle and 8 gallons of mixture were reportedly used for each (or both) treatment(s).

The report of 11/15/90 describes the alleged results of a single treatment of a 5,000-square-foot are of mixed grasses. One 16-ounce bottle, diluted with 16 gallons of water, was used for this treatment. The report states that mole activity in the treated area ceased although there was mole activity

> ". . . in untreated area three to four feet outside of treated area two days after treatment."

In the efficacy review of 6/19/90, I went fishing for any information that the applicant might have concerning the effectiveness of the product. Specifically, I requested that the Picketts

> "Submit complete reports of valid research which demonstrates effectiveness of this formulation. Do not submit testimonials from 'satisfied customers' in place of valid efficacy data."

What has been submitted amounts, at best, to glorified testimonials. The reports do not indicate how the product was mixed and applied nor do they provide much information regarding how initial and continued mole presence was determined. If Pickett was looking primarily at surface feeding runs, it is possible that he could have gotten false positive results as such runs may only be used once. The fresh activity reported in the report of 11/15/90 that appeared just outside of the treated area may have been due to a mole from the treated area who happened to start feeding off the edge of the treated area. On the other hand, it is possible that this product, made from castor oil and Dove soap, did repel the animal to outside the treated area. It is possible that moles feeding in treated areas ingest enough castor oil to either make them sick and/or to make them not

want to taste any more.

EPA's protocols for field testing mole toxicant products call for the marking of 20 distinct mole burrow systems. Every other system is to be treated. Three such series of tests are to be conducted. Since those guidelines were developed, no one has submitted to EPA results of a full series of mole efficacy tests. At this point, I am not sure whether the general methods prescribed for mole toxicants are appropriate for testing mole repellents (or even mole toxicants). What I am sure of is that the tests submitted by the Picketts do not adequately demonstrate product effectiveness.

There are two basic reasons for requesting efficacy data for a "non-public-health" product like this: 1) to determine whether the claims have any validity, and 2) to determine whether the application methods and rates prescribed on the proposed label are appropriate. While Eldon Pickett reports that the dilution rate (1-ounce of product per gallon of water) prescribed on the proposed label was used in two of these tests, the tests really do not establish whether the product actually worked. To do so would require more formal studies run by an individual familiar with vertebrate pesticide efficacy research and the design of experiments.

It is not clear to me why Eldon Pickett's reports were filled out in both ink and typing nor is it clear to me why he waited until the Fall of 1990 to write-up studies conducted many months earlier. Perhaps this was due to EPA's asking for data. If so, one wonders whether field trials actually were conducted on the dates indicated in the reports (or at all). As I remain concerned that this product might be bogus, I will ask that formal efficacy studies be conducted. If this testing can be accomplished on less than 10 acres, the Picketts will not need an EUP.

The revised proposed label submitted on 11/21/91 bears two panels of text. The left (apparently "front") panel includes the product name, a "COMPOSITION" statement listing the ingredients, and some precautionary statements including some text in spanish. Between the product name and "COMPOSITION" is the following paragraph of claims:

> "Mole-Med is an old time way to rid your yard of moles. This formula has been used successfully for years. The ingredients do not kill the mole, but the mole will not live or tunnel in an area that has been treated with Mole-Med."

The last sentence makes an absolute claim of general repellency for the product that could be disproved by a single failure. The first two sentences imply that this

product has been around, in some form, for many years and is a tried-and-true good ol' home remedy. As I doubt that this formulation ever has been federally registered, it would appear either that the first two sentences are false or that the allude to years of informal and/or illegal use.

The "instant misbranding" statements (e.g., "ENVIRONMENTALLY SAFE," "contains no harmful chemicals," and "NOT HARMFUL TO ANIMALS, BIRDS OR PLANTS") that appeared in the labels discussed in the efficacy review of 6/19/90 have been dropped from the revised proposed labels.

The "back panel" of the revised proposed label is badly organized. The heading "DIRECTIONS FOR MOLES" appears near the top of the column, under "SHAKE WELL BEFORE USING." Following these application directions are various precautionary statements. Below that are "DIRECTIONS FOR USE" which include the mandatory "It is a violation . . ." statement and a dilution table. Under "CONCLUSIONS," I indicate a reorganized format.

202.0 CONCLUSIONS

1. The brief reports pertaining to use of the product are not sufficient to demonstrate product effectiveness. The reports were prepared 6-10 months after the treatments were said to have been made. The procedures used for assessing pretreatment and posttreatment activity by moles are not described sufficiently. There is little quantification of results and no systematic attempt to compare in mole activity over time in treated and untreated areas.

   Before we can consider this product for registration, we must see data which indicate bases for all claims that you make for this product. Such data also would assist us in determining the appropriateness of your proposed dilution and application directions. These data must come from experimental field studies designed to isolate the effects of your product from other factors which might affect mole activity in treated areas. These studies must monitor mole activity before and after the time of treatment in treated areas and in similarly infested untreated areas nearby. Conduct of such research also must conform to EPA's "GOOD LABORATORY PRACTICE STANDARDS" (40 CFR, Part 160).

   We suggest that you contact biological or agricultural science departments of universities in Indiana and nearby states (e.g, Indiana State University, Purdue University, Michigan State University, Bowling Green State University, etc.) to find individuals who might be



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interested in running field trials for you at reasonable cost. Before running such studies, you should submit a protocol describing the planned research. If this protocol requires 10 or more acres of land to be treated, you will be required to obtain an Experimental Use Permit (see 40 CFR, Part 172). If your consultant wishes to discuss the protocol while it is under development, he or she may contact Dr. William W. Jacobs of my staff at 703-557-4406.

2. On the front panel of the proposed label, change 'REPELLANT" to "REPELLENT."

3. Although your revised proposed label states that this "formula has been used successfully for years," we are not aware that this product or another like it ever has been registered. As establishing the validity of this sentence and the sentence which precedes it on the front panel of the proposed label might entail self-incrimination, we suggest that you delete these sentences.

   The third product promotional statement on the front label panel provides a claim of absolute repellency that could be proven false by a single instance of product failure. This statement should be deleted. A modified version of this statement basically would state that the product is intended to be a mole repellent. This information appears elsewhere on the label.

4. The back panel of the proposed label for this product is badly organized. Reorganize this panel as indicated below.

   a. Move "PRECAUTIONARY STATEMENTS" to the top of the page, followed by "HAZARDS TO HUMANS AND DOMESTIC ANIMALS," and the "WARNING" paragraph.

   b. Follow the "WARNING" section with "DIRECTIONS FOR USE," which should be organized and revised as follows:

      "DIRECTIONS FOR USE

      It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

      USE RESTRICTIONS: For repelling moles [indicate species for which you claim effectiveness] already present from lawns and [if you also intend to make this claim] to keep

moles from entering treated areas. [Add suitable additional comments, as appropriate regarding limitations on use such as types of plants, if any, that product can damage, periods of time that should elapse between treatment and restoration of lawn to general use such as playing on it, mowing, watering, etc.]

MIXING DIRECTIONS: Mix with water at a rate of one ounce of MOLE MED per gallon of water. Use the DILUTION TABLE below to determine the amount of mixture to prepare for the area that you intend to treat.

DILUTION TABLE

| Amount of | Water | Area Covered |
|---|---|---|
| 1 Oz. | 1 Gal. | 312 Sq. Ft. |
| 2 Oz. | 2 Gal. | 625 Sq. Ft. |
| 16 Oz. | 16 Gal. | 5,000 Sq. Ft. |
| 32 Oz. | 32 Gal. | 10,000 Sq. Ft. |

SELECTION OF TREATMENT AREAS: The presence of moles may be indicated by a network of surface ridges in the turf or by a series of conical mounds of earth pushed up from deep burrows. Treated areas should encompass such evidence of moles' presence.

APPLICATION DIRECTIONS: Apply MOLE MED with a hand-held sprayer or sprinkling can to entire area that is to be rid of moles or protected from moles. Cover treated area thoroughly with mixture. Water treated area for 25 minutes. If soil is dry, water area thoroughly prior to treatment. If heavy rains occur shortly after treatment, application may have to be repeated.

c. Follow the "DIRECTIONS FOR USE" section with "STORAGE AND DISPOSAL," "STORAGE," "PESTICIDE DISPOSAL," and "CONTAINER DISPOSAL."

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
April 30, 1991



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